IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

John O'Mahony et al. Atty. Ref.: 3659-67

Serial No. 10/601,574 TC/A.U.: 3761

Filed: June 24, 2003 Examiner: DEAK, Leslie R.

For: METHOD AND APPARATUS FOR BLOOD WITHDRAWAL AND INFUSION USING A PRESSURE CONTROLLER

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June 17, 2009

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the Final Office Action dated November 17, 2009.

A notice of appeal was filed **March 17, 2009**. A petition is made for a one month extension of time.

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REAL PARTY IN INTEREST

The real party in interest is CHF Solutions Inc., privately held Delaware corporation having a principal office in Brooklyn Park, MN.

RELATED APPEALS AND INTERFERENCES

Other than mentioned below, the appellant, the undersigned, and the assignee are not aware of any related appeals, interferences, or judicial proceedings (past or present), which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

This application was subject to Appeal 2007-0696 in which the BPAI affirmed a prior final rejection on January 16, 2008.

STATUS OF CLAIMS

Claims 82 to 85 are pending and have been rejected. Claims 1 to 36, 40, 44, 58 to 60 and 73 have been cancelled. Claims 37 to 39, 41 to 43, 45 to 57, 61 to 72, and 74 to 81 are withdrawn in view of a PTO restriction requirement. No claims have been allowed.

STATUS OF AMENDMENTS

A Response After Final was submitted on January 21, 2009, that made minor grammatical changes to claims 82 and 84. This Response was entered by the Examiner as stated in the Advisory Action of February 3, 2009.

SUMMARY OF CLAIMED SUBJECT MATTER:

The inventions of rejected claims 82 to 85 relate to a leak detector (117) for an extracorporeal blood circuit having blood tubing (104, 105) and a filter (108), and connectable to a blood pump 113 (Qb). [Specification (Spec.) p. 18, ln. 23 to p. 19, ln. 2]. The leak detector and blood circuit are shown schematically in Figure 2 of the application which is reproduced on the next page.

The blood pump periodically reverses the direction of blood flow through the tubing that withdraws and returns blood to the patient through withdrawal and return needles 102, 103. [Spec. p. 9, lns. 17-18; p. 32, ln. 24 to p. 33, ln. 25; p. 46, lns. 8-19; and original claim 4 to 9 and 20, and Abstract]. Reversing the blood flow is used to clear occlusions that can occur in the vein from which blood is being withdrawn. [Spec. p. 9, lns. 18-20]. A vein may collapse due to excessive withdrawal of blood. The collapsed vein occludes the inlet to the withdrawal line needle (102) and prevents blood flow into the blood circuit. When an occlusion is detected, the pressure controller may first slow or stop the blood pump and, if necessary, reverse the blood pump to clear the occlusion. [Spec., p. 32, ln. 24 to p. 33, ln. 4].

A leak detector (117) monitors the blood flow through the tube 104 to detect air bubbles in the blood. [Spec., p. 18, lns. 10-16]. Air in the blood tube indicates a disconnection or leak in the tube. [Spec., p. 25, lns. 24-6 and p. 28, lns. 8-12]. Air bubbles are not to be infused into the veins of the patient. [Spec. p. 9, ln. 22]. When an air bubble is detected, the controller signals an alarm that a disconnection has occurred in the blood circuit and stops the pump. [Spec., p. 28, lns. 8-12]. The leak detector senses

air bubbles regardless of the direction of blood flow in the tube. [Spec. p. 28, lns. 8 to 26]. In particular, the disconnect detection algorithms (that are used to sense air in the blood lines) are applied during reverse blood flow. [Spec. p. 32, ln. 28 to p. 33, ln. 5]. Accordingly, leak detection is performed during reverse blood flow and normal flow through the blood circuit.

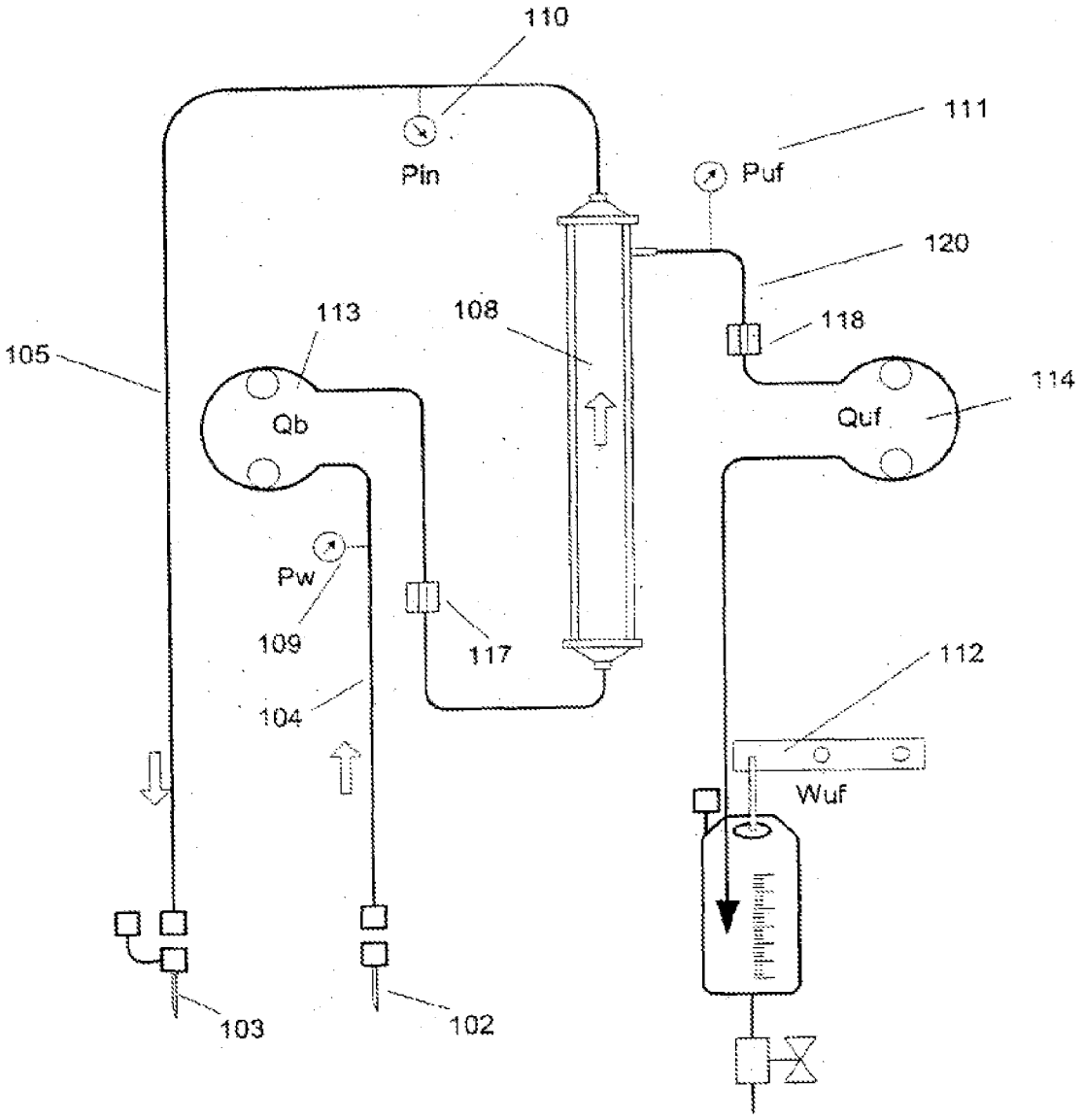


Fig. 2

Annotated version of independent claims 82 and 84 are set forth below and are representative of the claims on appeal:

CLAIM 82 A leak detector for a sterile contiguous fluid line (104, 105) for infusing a patient, the fluid line including a draw line (104) connectable to at least one patient access (102) and a return line (105) directly connected to said at least one patient access (103, Spec. p. 9, lns. 17-18; p. 32, ln. 24 to p. 33, ln. 25; p. 46, lns. 8-19), said detector comprising:

a portion of the fluid line adapted to be interoperable with a pump actuator (113, Spec. p. 18, ln. 23 to p. 19, ln. 2) such that fluid may be conveyed therethrough;

a filter (108, Spec. p. 16, lns. 6-17), or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;

said pump actuator (113; Spec. p. 16, ln. 27 to p. 17, ln 21) having a first configuration in which a positive pressure is generated in said return line (105) and a second configuration in which a negative pressure in said return line, whereby a flow through said return line and said at least one patient access (103) may be reversed (Spec. p. 32, ln. 28 to p. 33, ln. 5, *see also*, p. 9, lns. 18-20) when the pump actuator switches from the first configuration to the second configuration, and

a blood leak sensor (117; Spec. p. 28, lns. 8 to 26) coupled to said fluid line, wherein the return line (105) is directly

connected to said at least one patient access and forms a continuous fluid passage substantially free of gases.

CLAIM 84. A blood flow direction control device for a sterile contiguous fluid line (104, 105) for infusing a patient, the fluid line including a draw line (104) connectable to at least one patient access (102) and a return line (105) directly connected to said at least one patient access (103, Spec. p. 9, lns. 17-18; p. 32, ln. 24 to p. 33, ln. 25; p. 46, lns. 8-19), said device comprising:

a portion of the fluid line adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;

a filter (108, Spec. p. 16, lns. 6-17), or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;

at least a wetted portion of the portion of the fluid line and the pump actuator (113; Spec. p. 16, ln. 27 to p. 17, ln 21) having a reverse flow operational mode in which the actuator generates a negative pressure in said fluid line, and a flow through said return line and said at least one patient access is

reversed, (Spec. p. 32, ln. 28 to p. 33, ln. 5, *see also*, p. 9, lns. 18-20) and

wherein the return line is directly connected to said at least one patient access and forms a continuous fluid passage substantially free of gases(103, Spec. p. 9, lns. 17-18; p. 32, ln. 24 to p. 33, ln. 25; p. 46, lns. 8-19).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the subject matter of claims 82 to 85 would have been obvious under 35 U.S.C. §102(b) by Kenley et al (US Patent 5,690,831).

ARGUMENT

A. Kenley et al Does Not Render Obvious Claims 82 to 85

The claims require the following elements that are not disclosed in Kenley:

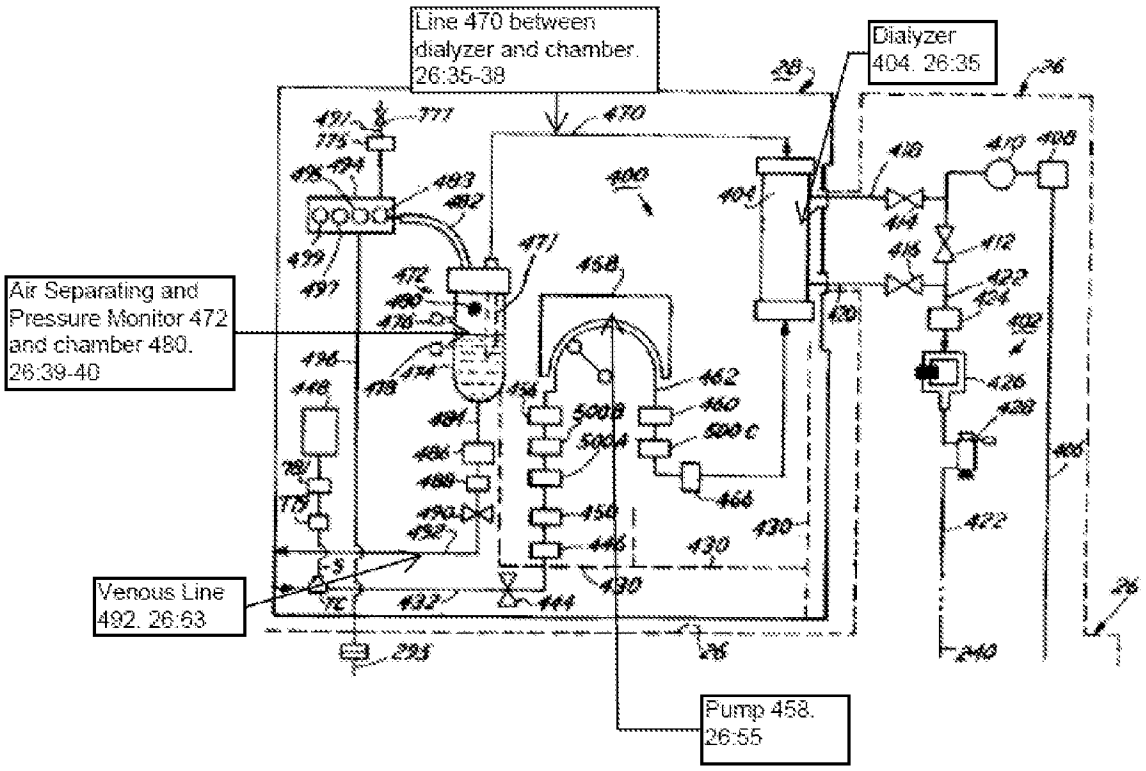
a) return line directly connected to said at least one patient access that forms a continuous fluid passage substantially free of gases, and

b) a reverse flow in the return line and the patient access when the pump or pump actuator is reversed.

The final rejection states that return line 470 in Kenley is "directly *fluidly* connected" to a patient access. Independent claims 82 and 84 require the return line to be "directly connected" to the patient access. The term "fluidly" is not used in the claims to describe the connection between the return line and the patient access. The return line 470 in Kenley is directly connected to air-separating and pressure monitoring chamber 472. The return line 470 is not directly connected to a patient access device.

The figure below is an annotated Figure 13 from Kenley et al and shows that the blood line 470 is not directly connected to a patient access.[1]

[1] In the following figure, the references to the column and lines of Kenley et al are indicated in the text boxes.



Kenley teaches away from reversing blood flow in a patient access. Kenley discloses a clamp 490 that prevents reverse flow in return line 492 that leads to a patient access device. When the Kenley pump is reversed, the blood return line 492 is clamped shut to ensure that blood is not drawn out of the patient, into a patient access device and through the return line 492. Kenley, col. 26, lns. 57-60. When the pump is reversed, blood is drawn out of chamber 480 into line 470, air is drawn into chamber 480 and there is no flow through blood line 484, 492 due to the closed clamp 490. Kenley, col. 26, lns. 58-64.

The Final Office Action and Advisory Action applies as a single line the venous return line 492 and venous line 484, where venous line 484 is upstream of the clamp and the venous return line 492 is entirely downstream of the clamp 490. The venous return line 492 is directly connected to a patient access. The venous line 484 is not directly

connected to a patient access. The clamp prevents any reverse flow direction in the venous return line 492. Kenley, col. 26, lns. 35-37 ("The bottom of the chamber 474 is connected to a line 484 having an ultrasonic air bubble detector 486, a blood sensor 488 and a clamp 490 and is connected to the venous line 492 which leads to the patient."). By teaching a clamp to prevent reverse flow at the access point, Kenley teaches away from the present invention in which reverse blood flow occurs at the access point.

The claims require "a continuous fluid passage substantially free of gases." The fluid passage disclosed in Kenley includes an air-separating and pressure monitoring chamber 472 that is partially filled with air. Kenley, col. 26, lns. 39-64. Air in the blood bubbles to the top of the chamber and is vented. Blood settles in the chamber and ultimately drains out of the chamber bottom and into return line 492. The chamber receives blood fluid entering through line 470 and has an upper outlet for air (which is a fluid) and a lower outlet for blood (which is also a fluid). The air region of the chamber is included in the fluid passage and is a gas portion of the fluid passage. Because of the air region and vent, the chamber 472 in Kenley is not a "continuous fluid passage substantially free of gases."

It would not have been obvious to modify Kenley to form the claimed invention. Kenley teaches away from a gas free fluid passage and from reversing blood flow in a return patient access device. There is no suggestion or motivation evident from Kenley to make the modifications needed to form the claimed invention. Accordingly, claims 82 and 84, claims 82 to 85 are not rendered obvious by Kenley.

B. Amendment To Claims Address Concerns Raised in Prior BAPI Decision

In the prior appeal, the BPAI affirmed the prior final rejection. The Board stated that "[t]his issue turns on whether Kenely's line 450 is a return line which is 'connectable' to at least one patient access." Decision on Appeal, p. 3. The Board found that "although line 470 does not directly connect to a patient access, it is nonetheless connected to the patient access through chamber 471 and line 492." Decision on Appeal, p. 4. The claims have been amended to require "a return line directly connected to said at least one patient access." As discussed above, this requirement for a direct connect between the return line and the patient access addresses the concern that the blood line 470 in Kenley is indirectly connected to a patient access through the chamber 471 and line 492. Further, this requirement distinguishes Kenley that teaches away from reverse blood flow at the access point normally used for blood infusion.

CONCLUSION

In conclusion it is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

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CLAIMS APPENDIX

Claims 82 to 85 are on appeal and are as follows:

82. A leak detector for a sterile contiguous fluid line for infusing a patient, the fluid line including a draw line connectable to at least one patient access and a return line directly connected to said at least one patient access, said detector comprising:

a portion of the fluid line adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;

a filter, or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;

said pump actuator having a first configuration in which a positive pressure is generated in said return line and a second configuration in which a negative pressure in said return line, whereby a flow through said return line and said at least one patient access may be reversed when the pump actuator switches from the first configuration to the second configuration, and

a blood leak sensor coupled to said fluid line,

wherein the return line is directly connected to said at least one patient access and forms a continuous fluid passage substantially free of gases.

83. A detector line as in claim 82, wherein said pump actuator in the second configuration is further configured to reverse a flow in both said return line and said draw line.

84. A blood flow direction control device for a sterile contiguous fluid line for infusing a patient, the fluid line including a draw line connectable to at least one patient

access and a return line directly connected to said at least one patient access, said device comprising:

a portion of the fluid line adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;

a filter, or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;

at least a wetted portion of the portion of the fluid line and the pump actuator having a reverse flow operational mode in which the actuator generates a negative pressure in said fluid line, and a flow through said return line and said at least one patient access is reversed, and

wherein the return line is directly connected to said at least one patient access and forms a continuous fluid passage substantially free of gases.

85. A blood flow direction device as in claim 84, wherein reverse a flow is achieved in both said return line and said draw line during the reverse flow operational mode.

EVIDENCE APPENDIX

NONE.

RELATED PROCEEDINGS APPENDIX

NONE.